UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, Plaintiff, -against- NOVARTIS PHARMACEUTICALS CORPORATION, Defendant.	**11 CIV. 8196 (CM)**

NOVARTIS PHARMACEUTICALS CORPORATION'S REPLY MEMORANDUM OF LAW IN SUPPORT OF ITS RULE 12(B)(6) MOTION TO DISMISS THE AMENDED COMPLAINT IN INTERVENTION OF THE UNITED STATES OF AMERICA

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Defendant Novartis Pharmaceuticals Corporation ("NPC") submits this Reply Memorandum of Law in further support of its motion to dismiss, pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure, the Amended Complaint in Intervention ("Amended Complaint") filed by the United States of America. (The United States of America is referred to collectively with the intervening states as the "Government", and the arguments made below apply with equal force to the complaints and opposition papers filed by the states.)

PRELIMINARY STATEMENT

Nearly half the arguments made by the Government in opposition to NPC's opening brief (including its lengthy discussion, in loaded language, of the factual assertions set forth in the Amended Complaint) have nothing to do with the legal question posed by the Court in its May 29, 2014 Memorandum Decision and Order. -- F. Supp. 2d --, 2014 WL 2324465 (S.D.N.Y. May 29, 2014) ("Novartis I"). The question raised—and the question that is the focus of NPC's motion—is whether the Government must plead at least some causal nexus between (i) the alleged kickbacks NPC purportedly paid to specialty pharmacies to influence improperly the prescribing decisions of physicians with respect to Myfortic; and (ii) the actual prescribing decisions of those physicians, which resulted in claims for reimbursement of Myfortic that the Government now challenges as "false" under the False Claims Act ("FCA"), 31 U.S.C. § 3729. (In the case of Exjade, the question is whether the Government must plead a causal nexus between the alleged kickbacks purportedly paid to BioScrip and the decisions of patients taking Exjade to order doctor-prescribed refills of that medication that were "not needed or clinically appropriate".)

As NPC demonstrated in its moving papers, the plain language and intent of the FCA and the Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b(g), together with relevant

caselaw, require the Government to plead a sufficient causal nexus. Among other things, the AKS explicitly provides that a claim submitted to the government for reimbursement is "false or fraudulent" for purposes of the FCA where the claim "includes items or services resulting from" a violation of the AKS. 42 U.S.C. § 1320a-7b(g) (emphasis added). Where it actually addresses this legal issue, the Government does not (because it cannot) dispute that the FCA requires causation. Although it avoids the term "resulting from", the Government acknowledges that the FCA implicates only those claims for reimbursement that are "tainted by" or "connected to" kickback payments, a clear concession that there must be a link between the kickback and the "items and services" included in the challenged claim.

Rather than dispute the causation requirement, the Government argues that it has met that requirement by pleading kickback payments to specialty pharmacies and the subsequent "shipment" by those pharmacies of Myfortic and Exjade to patients. But the Government's position ignores entirely the fact that there can be no "shipment" of Myfortic or Exjade by a pharmacy without a prescription written by a doctor or a refill ordered by a patient. The Government's position similarly ignores the fraudulent scheme as articulated in its own Amended Complaint, which asserts that NPC paid kickbacks to specialty pharmacies so that those pharmacies would influence the prescribing and refill decisions of doctors and patients. While the Government may now wish to pursue a different FCA claim—one that does not depend upon the corruption of doctor and patient treatment decisions—that simply is not the case it has brought.

ARGUMENT

NPC's motion to dismiss pursuant to Rule 12(b)(6) is based on the Government's failure to plead a sufficient causal nexus between the fraudulent scheme it alleges and the

resulting claims for Myfortic and Exjade that it challenges as false under the FCA. Despite the narrow focus of NPC's motion, the Government spends considerable space in its opposition describing the fraudulent scheme set forth in the Amended Complaint and criticizing NPC for "distort[ing] the Government's amended complaint by misrepresenting and selectively omitting many of its key allegations". (Gov't Opp. at 4-6; see also id. at 14-16.) This criticism is unwarranted: NPC accurately describes the key allegations of the Amended Complaint, including that the alleged kickbacks to BioScrip took the form of referring additional Exjade patients to BioScrip, and that the alleged Myfortic kickbacks were meant to induce pharmacists to convince doctors to switch patients to Myfortic, and to keep patients on Myfortic as opposed to a competitor drug. (Compare Gov't Opp. at 4-6 with NPC Br. at 5-6.) It also is entirely irrelevant. For purposes of this motion, NPC accepts as true (as it must), the factual assertions of the Amended Complaint, including the fraudulent scheme pleaded by the Government. The issue raised by NPC's Rule 12(b)(6) motion (as opposed to its Rule 9(b) motion) is not whether the fraudulent scheme is sufficiently pleaded; it is whether the Government has sufficiently linked that scheme to the claims for reimbursement it challenges as false.

Similarly unfounded is the Government's contention that NPC fails to address—and has somehow "waived"—its ability to challenge the Government's "legal falsity" argument (to the extent the Government even continues to make it), namely that a pharmacy's alleged express false certification is sufficient in and of itself to plead causation under the FCA. (Gov't Opp. at 16-18.) NPC directly addressed that issue. (NPC Br. at 15-16 & n.3 ("[f]alsity and causation are distinct requirements, both of which the Government must plead").)

NPC next turns to the Government's remaining arguments—the only arguments even arguably relevant to the causation issue raised in NPC's motion.

I. THE GOVERNMENT MUST PLEAD THAT THE CHALLENGED CLAIMS ARE CAUSALLY LINKED TO THE ALLEGEDLY FRAUDULENT SCHEMES.

A. The Plain Language of the AKS Imposes a Causation Requirement.

The Government asserts an FCA claim predicated on an underlying violation of the AKS. The AKS explicitly provides: "[A] claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of [the False Claims Act]". 42 U.S.C. § 1320a-7b(g) (emphasis added). Accordingly, the AKS requires a causal nexus between the underlying AKS violation and the "items or services" that the government is being asked to reimburse. (NPC Br. at 12-15.)

Although it uses the words "tainted by" and "connected to" as opposed to the "resulting from" language in the AKS, the Government does not dispute that the FCA imposes a causation requirement. (See, e.g., Gov't Opp. at 14 ("[C]laims are false for purposes of FCA to the extent they include Exjade and Myfortic shipments connected to or tainted by Novartis's offer of kickbacks to the pharmacies in the forms of patient referrals and rebates."); see also State Opp. at 3 ("the plain language of the phrase 'resulting from' indicates that there must be a connection between the kickback and the claim").) Instead, the Government focuses on "items and services" and argues that because the "items and services" at issue here are "shipments" of Exjade and Myfortic—not "prescriptions" of those drugs—it has adequately pleaded causation. (See Gov't Opp. at 4-5, 14-16.) The Government's position has no merit.[1]

[1] The Government mischaracterizes NPC's discussion (NPC Br. at 9-10) of the purpose of the 2010 Amendment to the AKS but agrees that the Amendment was a "clarification" and did not impose a new causation requirement (Gov't Opp. at 1-2, 7). The Government therefore must allege the required causal nexus for all claims asserted in the Amended Complaint, including those made before the 2010 Amendment.

First, the distinction the Government attempts to draw between "prescriptions" of Exjade and Myfortic and "shipments" of those drugs is a distinction without a difference. There is no question that specialty pharmacies cannot ship Myfortic to patients without a valid prescription written by a doctor. Nor can they ship refills of doctor-prescribed Exjade to a patient absent a refill request from that patient. Thus, even if the "items and services" included in the claims at issue are characterized as "shipments" of Myfortic and Exjade, those shipments can only be made if a doctor prescribes Myfortic or a patient orders an Exjade refill pursuant to an existing physician's prescription. That means such shipments "result from" or are "tainted by" alleged kickback payments to pharmacies only where pharmacies influence the doctor's prescription decision or the Exjade patient's refill decision. NPC characterized the relevant "items and services" as "prescriptions" of Exjade and Myfortic (NPC Br. at 14-15), because that is the first link in the causal chain between the alleged AKS violation and the claim for reimbursement. That the Government chooses to start with the second link—the dispensing of the drug ordered by the doctor or patient—does not somehow alter the causation requirement; it merely begs the question of who authorized the shipment (doctor/patient) and whether that authorization was somehow "connected to" (Gov't Opp. at 14) NPC's alleged kickback payments to specialty pharmacies.

Second, and similarly, the Government's contention that FCA causation is sufficiently pleaded because the Amended Complaint alleges that NPC paid kickbacks to pharmacies and those pharmacies "shipped" Exjade and Myfortic removes doctors and patients from the equation entirely. Not only does that destroy the nexus that the Government itself admits is required, but it ignores the fraudulent scheme as set forth in the Amended Complaint.

NPC does not argue (and has never argued) that to plead sufficiently an FCA

violation there must always be an allegation of physician taint. There may well be circumstances where the government asserts that a pharmacist has the authority to make treatment decisions—for example, where the doctor merely prescribes a generic form of a particular medication and the pharmacist is the one who chooses which of two generics to dispense. In that scenario, if one of the two generic manufacturers paid a kickback to the pharmacist, and the pharmacist then dispenses that manufacturer's generic drug, the subsequent claim for reimbursement would almost certainly meet the "resulting from" requirement, at least at the pleading stage. But that is not the fraudulent scheme the Government asserts in this case. Here, the Amended Complaint expressly alleges a fraudulent kickback scheme and resulting FCA violation that depends upon the "tainted" decisions of doctors and patients. The Government's theory (regardless of how it now chooses to characterize that theory in its opposition brief) is that NPC paid specialty pharmacies to influence improperly the treatment decisions of doctors and Exjade patients. The Amended Complaint makes dozens of references to this critical "link" between the purported kickback payments and the doctor prescriptions/patient refills that led to the challenged claims for "items and services". (See, e.g., Am. Compl. ¶¶ 2, 4-5, 7, 61-69, 74, 77, 95, 97, 101, 104, 106, 115-18, 143; see also 3/14/14 Hr'g Tr. at 6, 7-9.) The Government cannot simply choose at this point to "remove" the doctor/Exjade patient from the alleged scheme, and its attempt to do so is telling, considering the voluminous discovery it already has received during its pre-suit investigation. If the required connections exist between the specialty pharmacies and the doctors/patients at issue, the Government should be able to plead them.

B. A Causation Requirement Is Consistent with the Purpose of the AKS and FCA.

In its opening brief, NPC demonstrates that the causation requirement is consistent with the combined goals of the AKS and FCA: to prohibit use of financial incentives to compromise a healthcare provider's independent medical judgment, and to protect the

government from any monetary loss resulting from that compromised judgment. (NPC Br. at 16-18.) The Government makes two arguments in response, neither of which is persuasive.

The Government first contends that NPC is asking the Court "to add a 'but for cause' requirement to the 'legal falsity' because, it claims this is 'consistent with the purpose of the AKS and FCA'". (Gov't Opp. at 11.) NPC is not asking the Court to "add" anything based on the purpose of the AKS and FCA. The plain language of the AKS makes clear that only those claims which include "items and services resulting from" the alleged AKS violation can form the basis for an FCA cause of action. NPC merely cites the purpose of the AKS and FCA to demonstrate that the causation requirement is consistent with their combined statutory goals. See Abramski v. United States, 134 S. Ct. 2259, 2267 (2014) (Gov't Opp. at 9). The Government's reference to "legal falsity" in this context makes no sense. NPC submits that "legal falsity" and "causation" are two distinct requirements (NPC Br. at 15-16); it certainly never argued that causation should somehow be added to "legal falsity".

Finally, and most important, NPC does not claim anywhere in its opening papers that the Government must plead "but for" causation in the sense that the influence of a specialty pharmacy was the "sole" reason for a physician's decision to prescribe Myfortic, or a patient's decision to order an Exjade refill. Nor does NPC argue that the Government must plead that the Myfortic prescriptions and Exjade refills at issue were "not medically necessary". (Gov't Opp. at 8.) At the pleading stage, NPC argues only that the Government is required to identify those doctors and patients whose treatment/refill decisions allegedly "resulted from" or were "tainted by" NPC's purported kickback payments to specialty pharmacies. Here, the Amended Complaint fails to specify which doctors and patients even spoke to specialty pharmacists, let alone those who were "tainted by" those interactions. (See NPC Br. at 1-2, 17-18; see also Gov't

Opp. at 14-16.) In other words, the Government cannot meet the most basic causation standard and therefore its repeated denouncement of a "but for" standard is a red herring.[2]

The second argument raised by the Government is that NPC wrongly claims that the AKS and FCA are "concerned only with whether doctors exercise independent clinical judgment". (Gov't Opp. at 11; see also State Opp. at 6.) The Government then cites a series of cases in which actors other than prescribing physicians have been the subject of FCA actions. (Gov't Opp. at 11-13.) NPC does not dispute—and has never disputed—that healthcare providers other than physicians can violate the FCA. (See, e.g., NPC Br. at 17 (AKS and FCA aimed at prohibiting the use of kickbacks to compromise "a healthcare provider's independent medical judgment" (emphasis added)).) As set forth above, however, the case brought by the Government concerns the treatment/refill decisions of doctors and patients—not the treatment/refill decisions of pharmacists. Accordingly, it is irrelevant that, in other cases based on different theories of fraud, pharmacists can violate the FCA.

C. Caselaw Is Consistent with the Requirement of a Causal Link.

In its opening brief, NPC shows that virtually all prior enforcement actions alleging FCA claims premised upon AKS violations in the healthcare context allege improper conduct by a physician, or at least some physician involvement, most typically that the physician himself or herself received a kickback. (NPC Br. at 18-21.) The Government does not challenge

[2] Notably, while NPC does not advocate a "but for" causation standard at this stage of the proceedings, there is substantial support for such a standard. See, e.g., Burrage v. United States, 134 S. Ct. 881, 889-91 (2014) (Gov't Opp. at 11 n.6) (construing phrase "results from" in context of the Controlled Substances Act and recognizing that "it is one of the traditional background principles against which Congress legislates that a phrase such as 'results from' imposes a requirement of but-for causation"); United States v. Shellef, 718 F.3d 94, 106-08 & n.5 (2d Cir. 2013) (Gov't Opp. at 10) (construing phrase "or other factors resulting from passage of time" in Speedy Trial Act as requiring something less than "but for" causation, yet providing examples of "other factors" consistent with "but for" standard).

these cases or NPC's premise. Instead, the Government relies heavily on United States v. Rogan, 517 F.3d 449, 453 (7th Cir. 2008), in which the government brought an FCA action against the defendant for participating in a scheme whereby a treatment center paid physicians kickbacks for patient referrals, and then submitted claims for treatment of those patients to Medicare and Medicaid. The principal issue before the court was whether damages should equal the value of all services claimed for reimbursement under the scheme, or whether the amount of damages should be reduced by the value of those services that actually were provided and medically necessary. Id. at 453. The court found that where the requirements for an FCA claim are met, a defendant cannot reduce the resulting damages for "valid" portions of claims. Id. Despite the Government's reliance, the language it cites from Rogan has no bearing on the threshold issue presented here, namely whether the Government has met the pleading requirements for an FCA violation in the first instance. Rogan simply is not a pleading case. The Government's reliance on Thompson and Pogue is similarly misplaced. (Gov't Opp. at 8.) Those cases concern whether a relator must plead actual loss to the government to survive dismissal, not the causal link necessary to demonstrate that claims are false because they were "tainted by" a kickback scheme. See U.S. ex rel. Thompson v. Columbia/HCA Healthcare Corp., 20 F. Supp. 2d 1017, 1047 (S.D. Tex. 1998); U.S. ex rel. Pogue v. Am. Healthcorp, Inc., 914 F. Supp. 1507, 1512-13 (M.D. Tenn. 1996).

II. THE GOVERNMENT'S THEORY OF FALSITY IS OVERBROAD.

The absence of a requirement that the Government allege a sufficient link between the alleged kickbacks and the "items and services" (that is, the Myfortic and Exjade prescriptions/shipments) included in the challenged claims for reimbursement would transform the potential scope of this case and all future FCA cases. (NPC Br. at 21-22.) The Government's two-pronged response to NPC's overbreadth concern merely highlights the issue.

According to the Government, "'resulting from' signals nothing more than that the taint from [a] kickback violation remains . . . irrespective of when a claim for that item or servi[c]e is made, which entity submits the claim, or what payment mechanism the Government uses to reimburse the claim". (Gov't Opp. at 10.) In other words, the Government concedes NPC's point that FCA liability based only on "legal falsity" in this case as alleged lacks temporal or any other limitation. (See, e.g., NPC Br. at 21 ("If a Myfortic kickback were paid to a pharmacist in year one, under the Government's theory all Myfortic claims submitted by the pharmacy in perpetuity are arguably false.").) At the same time, the Government contends that the "parade of horribles" cited by NPC will not occur because "the Government is not postulating a 'limitless' theory of taint; instead, under the Government's theory, falsity turns on whether the claim can be linked to the kickback violation". (Gov't Opp. at 18 (emphasis added); see also id. ("[U]nder the Government's theory, a prescription is not false if it was not issued in connection with the kickback violation.").)

Taken together, it is clear that the Government perceives the potential danger of an FCA claim based only on an alleged kickback scheme and "legal falsity". NPC respectfully submits that the Government's proposed solution—allegations of a "link" between the false claim and the kickback violation or, more precisely, allegations that a prescription was "issued in connection with the kickback scheme" is exactly right. These are the allegations that the Government must make in order to survive dismissal under Rule 12(b)(6); it fails to do so.

For the foregoing reasons, the Court should grant NPC's motion to dismiss the Amended Complaint in Intervention of the United States.

Dated: July 3, 2014

Respectfully submitted,

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